

Remarks/Arguments

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed October 31, 2008. Currently, claims 1, 7, 8, 11-19, 42-48, 50-52, 54-70, and 72-74 remain pending. Claims 1, 7, 8, 11-19, 42-48, 50-52, 54-70, and 72-74 have been rejected. With the Amendment, Applicant has amended claims 1, 7, and 51. Favorable consideration of the following remarks is respectfully requested.

Claim Objections

On page 2 of the Final Office Action, claims 1, 7, and 51 were objected to as including informalities. With regards to claim 1, the Examiner indicated that the phrase “arranged aligned” should be “arranged to be aligned”. With regards to claims 7 and 51, the Examiner indicated that the phrase “the side member comprises a flexible side sheath” should be “the side member is flexible”. With the Amendment, Applicant has amended claims 1, 7, and 51 accordingly.

Claim Rejections – 35 USC § 103

On page 2 of the Final Office Action, claims 1, 7, 8, 10, 12, 13, 15-19, 42-48, 50-52, 55, 56, 59-70, and 72-74 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (U.S. Patent No. 6,165,195) in view of Ryan et al. (U.S. Patent No. 6,576,009) or Shklovich (U.S. Patent No. 5,669,924) or Goicoechea et al. (U.S. Patent No. 5,609,627). After careful review, Applicant must respectfully traverse this rejection.

Turning to claim 1, which recites:

1. (Currently Amended) A catheter system for stent delivery to a vessel bifurcation, the vessel bifurcation having a main vessel and a branch vessel, comprising:
 - a catheter extending between a distal end and a proximal end, the catheter including a main vessel guidewire lumen that is adapted to receive a main vessel guidewire;
 - a stent being disposed over the catheter, the stent having a side hole through a wall thereof;
 - a first catheter radiopaque marker arranged on the catheter distal of the stent;
 - a second catheter radiopaque marker arranged on the catheter proximal of the stent;
 - a third catheter radiopaque marker arranged on the catheter aligned with the side hole of the stent;
 - a side member disposed adjacent the catheter, the side member extending

between a free distal end and a proximal end, the side member including a branch vessel guidewire lumen that is adapted to receive a branch vessel guidewire, the side member being fixedly attached to the catheter at a location proximal the stent, the free distal end of the side member arranged extending through the side hole in the stent;

a first side member radiopaque marker positioned on the side member at the free distal end of the side member;

a second side member radiopaque marker positioned on the side member at a location spaced from the first side member radiopaque marker, wherein the second side member radiopaque marker is arranged to be aligned with the side hole of the stent when the free distal end of the side member extends into the branch vessel;

wherein the first and third catheter radiopaque markers and the first and second side member radiopaque markers are juxtaposed in a first configuration, and at least one of the first and second side member radiopaque markers is separated from the first and third catheter radiopaque markers in a second configuration to indicate that the free distal end of the side member is advancing into the branch vessel.

Nowhere do the cited references appear to teach or suggest at least “the side member being fixedly attached to the catheter at a location proximal the stent, the free distal end of the side member arranged extending through the side hole in the stent”, “a first side member radiopaque marker positioned on the side member at the free distal end of the side member”, “a second side member radiopaque marker positioned on the side member at a location spaced from the first side member radiopaque marker, wherein the second side member radiopaque marker is arranged to be aligned with the side hole of the stent when the free distal end of the side member extends into the branch vessel”, or “wherein the first and third catheter radiopaque markers and the first and second side member radiopaque markers are juxtaposed in a first configuration, and at least one of the first and second side member radiopaque markers is separated from the first and third catheter radiopaque markers in a second configuration to indicate that the free distal end of the side member is advancing into the branch vessel”, as recited in claim 1.

In the Final Office Action, the Examiner asserts that “Wilson places markers on various elements but not multiple markers on each element as claimed”. The Examiner then turns to Ryan, Shakhovich, or Goicoechea for support and indicates that these references teach “that it was known to put multiple markers on the same element in order to determine orientation thereof”. The Examiner then concludes that “it would have been *prima facie* obvious to an ordinary artisan to put more than one marker on each element of Wilson for the same reasons

that the secondary references did". Applicant respectfully asserts that modifying the device of Wilson et al. to include marker configurations similar to Ryan, Shaknovich, or Goicoechea would still not arrive at the claimed invention.

In the Final Office Action, the Examiner relies on Figure 12L of Wilson et al. for support. With reference to Figure 12L, Wilson et al. appears to teach a main catheter assembly 50 including a guide wire lumen 53A having a distal end 53B with an expandable member 54 adjacent to the distal end 53B. A positioning guide wire lumen 55A is positioned partly on the catheter shaft and partly on the expandable member 54 and is configured for slidably receiving integrated stent –positioning guide wire 56A. (See column 16, lines 11-15). A stent 20 having a side aperture 25 is positioned over the expandable member and the positioning guide wire lumen 55A. The distal end 55B of the position guidewire lumen 55A “terminates in the middle of aperture 25” (column 16, lines 38-39). In this embodiment, a distal guide wire lumen 58 is attached to the balloon 54 outer surface and extends from the aperture 25 of stent 20 to essentially the distal end of the catheter. (See column 16, lines 41-44).

Wilson et al. teaches a method of using the device of Figure 12L in column 17, lines 22-42, which recites:

In an alternative method of implanting main-vessel stent 20 in main-vessel 6 as depicted in FIGS. 12J-12L, tracking guide wire 41A is advanced through guide wire lumen 55A and guide wire lumen 58 so that it advances distally of the distal end 51 of the catheter. Thus, guide wire distal end 41B is advanced into the main vessel so that it is distal of the side-branch vessel. Guide wire 56A, which until this point has remained within guide wire lumen 53A (see FIG. 12K), is advanced distally as depicted in FIG. 12L and advanced into the main vessel distally of the side-branch vessel. Guide wire 41A is then withdrawn proximally through guide wire lumen 58 until guide wire distal end 41B is able to exit guide wire lumen distal end 55B, as shown in FIG. 12L. Since guide wire lumen 55B is preformed and has bias, it will spring outwardly. Guide wire 41A can then be advanced into the side-branch vessel for further positioning. As the catheter 50 is advanced over the guide wires, distal portion 41B of the guide wire will push against the ostium of the side-branch vessel thereby insuring the location of main-vessel stent 20, and importantly aperture will align with the opening to the side-branch vessel 5.

From this, it is readily apparent that the distal end 55B of the positioning guidewire lumen 55A is provided at the middle of the aperture 25 of the stent 20. As such, the device of Wilson et al. does not appear to be capable of including a first marker at the distal end of the positioning guidewire lumen and a second marker spaced from the first marker and aligned with the aperture

of the stent, as the distal end of the positioning guidewire lumen is at the aperture of the stent. Thus, the asserted modification of Wilson et al. does not appear to teach or suggest “a first side member radiopaque marker positioned on the side member at the free distal end of the side member” and “a second side member radiopaque marker positioned on the side member at a location spaced from the first side member radiopaque marker, wherein the second side member radiopaque marker is arranged to be aligned with the side hole of the stent when the free distal end of the side member extends into the branch vessel”. Therefore, for at least these reasons, claim 1 is believed to be patentable over Wilson et al. in view of Ryan et al., Shaknovich, or Goicoechia et al. For similar reasons and others, claims 7, 8, 10, 12, 13, 15-19, and 42-48, which depend from claim 1 and include additional limitations, are believed to be patentable over Wilson et al. in view of Ryan et al., Shaknovich, or Goicoechia et al.

Turning to claim 50, which recites:

50. (Previously Presented) A catheter system for stent delivery to a vessel bifurcation, the vessel bifurcation having a main vessel and a branch vessel, comprising:

- a catheter having a distal end, a proximal end, and a main vessel guidewire lumen that is adapted to receive a main vessel guidewire;

- a stent having a side hole through a wall thereof, the stent being disposed over the catheter, wherein the stent hole is substantially alignable with a branch vessel when the stent hole is disposed substantially in the main vessel prior to expansion;

- a first catheter radiopaque marker arranged on the catheter distal of the stent;

- a second catheter radiopaque marker arranged on the catheter proximal of the stent;

- a third catheter radiopaque marker arranged on the catheter aligned with the side hole of the stent;

- a side member disposed adjacent the catheter, the side member having a distal end, a proximal end, and a branch vessel guidewire lumen that is adapted to receive a branch vessel guidewire, the side member being integral with the catheter at a location proximal the stent wherein the distal portion of the side member is disposed at least partially within a portion of the stent and at least partially extending through the side hole of the stent;

- a first side member radiopaque marker positioned on the side member at the distal end of the side member;

- a second side member radiopaque marker positioned on the side member at a location spaced from the first side member radiopaque marker, wherein the second side member radiopaque marker is aligned with the side hole of the stent when the distal end of the side member has passed through the side hole and into the branch vessel;

wherein said catheter radiopaque markers and said side member radiopaque markers are moveable from a first configuration to a second configuration, wherein in the second configuration at least one of the side member radiopaque markers is separated from at least one of the catheter radiopaque markers.

As discussed previously, nowhere do Wilson et al., Ryan et al., Shaknovich, or Goicoechea et al. appear to teach or suggest “the side member being integral with the catheter at a location proximal the stent wherein the distal portion of the side member is disposed at least partially within a portion of the stent and at least partially extending through the side hole of the stent”, “a first side member radiopaque marker positioned on the side member at the distal end of the side member”, or “a second side member radiopaque marker positioned on the side member at a location spaced from the first side member radiopaque marker, wherein the second side member radiopaque marker is aligned with the side hole of the stent when the distal end of the side member has passed through the side hole and into the branch vessel”, as recited in claim 50. Therefore, for at least these reasons, claim 50 is believed to be patentable over Wilson et al. in view of Ryan et al., Shaknovich, or Goicoechea et al. For similar reasons and others, claims 50-52, 55, 56, and 59-70, which depend from claim 50 and include additional limitations, are believed to be patentable over Wilson et al. in view of Ryan et al., Shaknovich, or Goicoechea et al.

Turning to claim 72, which recites:

72. (Previously Presented) A catheter system for stent delivery to a vessel bifurcation, the vessel bifurcation having a main vessel and a branch vessel, comprising:

- a catheter having a distal end, a proximal end, and a main vessel guidewire lumen that is adapted to receive a main vessel guidewire;
- a first stent having a side hole through a wall thereof, the first stent being disposed over the catheter;
- a first catheter radiopaque marker arranged on the catheter distal of the stent;
- a second catheter radiopaque marker arranged on the catheter proximal of the stent;
- a third catheter radiopaque marker arranged on the catheter aligned with the side hole of the first stent;
- a side member disposed adjacent and fixedly attached to at least one location on the catheter proximal the stent, the side member having a distal end, a proximal end, a branch vessel guidewire lumen that is adapted to receive a branch vessel guidewire, and at least two side radiopaque markers positioned on the side member, a first of the side radiopaque markers being spaced from a second of the side radiopaque markers, wherein the catheter positioned on the side member are

juxtaposed in a first configuration; and

a branch stent deployment device having a balloon, a guidewire lumen, an inflation lumen that is adapted to supply a fluid to inflate the balloon, and a branch vessel stent disposed over the balloon, wherein the branch stent deployment device is adapted to be advanced over the branch vessel guidewire;

wherein a distal portion of the side member is disposed within at least a portion of the first stent and extends through the side hole of the first stent.

As discussed previously, nowhere do Wilson et al., Ryan et al., Shaknovich, or Goicoechia et al. appear to teach or suggest wherein a distal portion of the side member is disposed within at least a portion of the first stent and extends through the side hole of the first stent”, as recited in claim 72. Therefore, for at least these reasons, claim 72 is believed to be patentable over Wilson et al. in view of Ryan et al., Shaknovich, or Goicoechia et al.

Turning to claim 73, which recites:

73. (Previously Presented) A catheter system for stent delivery to a vessel bifurcation, the vessel bifurcation having a main vessel and a branch vessel, comprising:

a catheter having a distal end, a proximal end, a main vessel guidewire lumen that is adapted to receive a main vessel guidewire, and catheter radiopaque markers positioned thereon;

a side member disposed adjacent the catheter, the side member having a distal end, a proximal end, a branch vessel guidewire lumen that is adapted to receive a branch vessel guidewire, and first and second side member radiopaque markers positioned thereon, the side member being integral with the catheter at a location proximal of the catheter radiopaque markers;

a stent having a side hole through a wall thereof being disposed over the catheter, wherein a first of the catheter radiopaque markers is arranged on the catheter distal of the stent, a second of the catheter radiopaque markers is arranged on the catheter proximal of the stent, and a third of the catheter radiopaque markers is arranged on the catheter aligned with the side hole of the stent; and

a branch stent deployment device having a balloon, a guidewire lumen, an inflation lumen that is adapted to supply a fluid to inflate the balloon and a branch vessel stent disposed over the balloon, wherein the branch stent deployment device is adapted to be advanced over the branch vessel guidewire;

wherein a distal portion of the side member extends through the side hole of the stent, and wherein said first and third catheter radiopaque markers and said first and second side member radiopaque markers are juxtaposed in a first configuration and separated in a second configuration.

As discussed previously, nowhere do Wilson et al., Ryan et al., Shaknovich, or Goicoechia et al. appear to teach or suggest “wherein a distal portion of the side member extends through the side hole of the stent, and wherein said first and third catheter radiopaque markers and said first and

second side member radiopaque markers are juxtaposed in a first configuration and separated in a second configuration”, as recited in claim 73. Therefore, for at least these reasons, claim 73 is believed to be patentable over Wilson et al. in view of Ryan et al., Shaknovich, or Goicoechea et al. For similar reasons and others, claim 74, which depends from claim 74 and includes additional limitations, is believed to be patentable over Wilson et al. in view of Ryan et al., Shaknovich, or Goicoechea et al.

On page 3 of the Final Office Action, claim 11, 54, and 58 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson, Ryan, Shaknovich, and Goicoechea, as applied to claim 1, and further in view of Dibie (WO 96/34580). Also on page 3 of the Final Office Action, claim 14 and 57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson, Ryan, Shaknovich, and Goicoechea, as applied to claim 1, and further in view of Davila et al. (U.S. Patent No. 5,851,464). After careful review, Applicant must respectfully traverse these rejections. As discussed previously, claims 1 and 50 are believed to be patentable over Wilson, Ryan, Shaknovich, and Goicoechea. Nothing in Dibie or Davila et al. appear to remedy the noted shortcomings. Therefore, for at least these reasons, claims 11, 14, 54, 57, and 58, which depend from one of claims 1 and 50, are believed to be patentable over the cited references.

Conclusion

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.\

Respectfully submitted,

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